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*Sir*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,745	03/11/2002	Craig Robert Bunt	P67399USO	1776
136	7590	10/01/2004	EXAMINER	
JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004			SIRMONS, KEVIN C	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/926,745		
	Examiner Kevin C. Sirmons	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 20 July 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 31-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 31-42 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

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## DETAILED ACTION

### *Drawings*

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the closure engaging the outlet (claim 31); a conduit (claims 34 and 42) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement-drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency.

Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 34, it is unclear what applicant regards as a conduit.

#### *Claim Rejections - 35 USC § 102*

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 31, 35 and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Factor WO 99/07346.

Factor discloses a delivery device comprising: (see entire document).

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-33 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winsel in view of Factor WO/99/07346 and further in view of Bunt WO 98/33452.

Winsel discloses a delivery device suitable for fluid delivery in a body cavity when inserted therein, said device comprising: a housing defining a barrel with an outlet (figs. 10a-10d), at least one deployable retention member in association with or forming part of the housing to retain the device in the body cavity (see needle), a piston disposed in said barrel and moveable to reduce the available volume (figs. 10a-10d); an expressible active agent including fluid within said barrel between said outlet and said piston (206), and a battery powered electrical circuit that includes a gas emitting battery in the housing or includes an electrolysis cell with hydrogel or electrolyte disposed in the housing (208 and applicant specification page 7), the circuit including a switch (202), to commence the generation of a gas that is confined within the housing (figs. 10a-10d); wherein the electrical circuit provides a continuous rate of gas production by the action of a continuous current to the electrolysis cell or gas emitting battery (col. 15), and the action of gas generation provides in vivo a constant sustained release of said active agent when the gas moves said piston (10a-10d).

Winsel does not disclose a closure engaging said outlet. Factor discloses a closure engaging said outlet (page 7). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Winsel to include a closure engaging outlet as taught by Factor for preventing fluid from leaking from the device.

As to claim 32, Winsel discloses the device substantially as claimed except for wherein the active agent is progesterone formulated in a liquid vehicle that can be aqueous, organic or non-organic. Bunt discloses progesterone formulated in a liquid vehicle that can be aqueous, organic or non-organic (see claim 2 and applicant's response

page 8). Therefore, it would have been obvious to one having ordinary skill in the art that the time the invention was made to substitute the liquid of Winsel with the liquid as disclosed by Bunt for treating women.

As to claim 33, water forms a part of progesterone; as to claim 39-41, (see above rejections).

#### *Allowable Subject Matter*

Claims 34 and 42 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

#### *Response to Arguments*

Applicant's arguments with respect to claim 31-42 have been considered but are moot in view of the new ground(s) of rejection.

#### *Conclusion*

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.



Kevin C. Sirmons  
Patent Examiner  
9/23/04